

REMARKS

Concurrently with this Response, Applicants also submit a petition for a two-month extension of time for filing a response, and the authorization to charge our Deposit Account 50-0552 for the amount of the requisite fee of \$490.00 and any fee deficiencies. The time for filing a response to the September 3, 2009 Office Action is thereby extended to February 3, 2010 and this Response is timely filed.

If any additional fees are deemed to be due at this time or an overpayment has been made, the Commissioner is authorized to charge said fee or credit said overpayment to Deposit Account No. 50-0552.

Status of Claims

Claims 1 to 83 were pending in the present application as reflected in preliminary amendment filed on October 31, 2007. Claims 36 to 63 were cancelled without prejudice in response to the Restriction Requirement dated May 28, 2009. New claim 84 has been added for consideration. Claims 1 and 64 have been amended. Claims 1 to 35 and 64 to 84 are now pending. It is respectfully submitted that no new matter was added in this amendment.

Rejection under 35 U.S.C 112

In the Office Action, the Examiner rejected claims 64 to 70 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. See Office Action, page 2, second full paragraph under section heading "Claim Rejections- 35 USC § 112."

Specifically, with respect to claim 64, the Office Action states that there is insufficient antecedent basis for the limitations "the strip of blisters" and "the aperture" in the second and third line of the claim. See Office Action, page 2, third full paragraph under section heading "Claim Rejections- 35 USC § 112." Claim 64 has been amended without prejudice in relevant part to recite "a strip of blisters past the blister piercing member" and the phrase "aperture in the housing" has been deleted.

In view of the foregoing, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, to claims 64 to 70 is respectfully requested.

Claim Rejection – 35 U.S.C. § 102

Piper (U.S. Patent No. 5,533,502)

Claims 1 to 5, 8 to 13, 31, 64, and 72 were rejected under 35 U.S.C. §102(b) as being anticipated by Piper (U.S. Patent No. 5,533,502).

Applicants respectfully direct the Examiner's attention to the current amendment to claim 1. Claim 1 now recites:

An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and an actuator pivotally mounted to the housing, said actuator being pivotable to sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister such that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it via the mouthpiece into the user's airway.

Applicants respectfully submit that claim 1, as amended, recites that the actuator is "pivotally mounted to the housing" and also to specify that the actuator is "pivotable" to cause the blister piercing member to puncture the lid of an aligned blister.

Although Piper discloses an actuator (carriage 24), it is only pivotable to enable each blister to be moved into alignment with a blister piercing member and does not pivot in order to pierce an aligned blister. On the contrary, in the device disclosed in Piper, the user must depress the carriage 24 in relation to the cover 12 so that the inlet and outlet conduits puncture the seal of an aligned medicament receptacle, as shown in Figures 3 and 4 and described at column 5, lines 66-67. Notably, compression of the carriage 24 actually ensures rotation of the carriage is prevented because registration keys 46 engage with registration gear 28, as stated at column 6, lines 2 to 5.

Piper does not show or teach “an actuator pivotally mounted to the housing, said actuator being pivotable to sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister” as recited in amended claim 1 of the present invention. Therefore, the inhaler as recited in claim 1 of the present invention is novel over Piper (U.S. Patent No. 5,533,502).

Claims 2 to 5, 8 to 13, 31, 64, and 72 depend either directly or indirectly from independent claim 1. Therefore, the response refers primarily to independent claim 1, and it is respectfully submitted that the patentability of the dependent claims 2 to 5, 8 to 13, 31, 64, and 72 follow at least for the reason of being dependent from independent claim that is patentable.

In view of the foregoing, withdrawal of the rejection under 35 U.S.C. §102(b), to claims 1 to 5, 8 to 13, 31, 64, and 72 is respectfully requested.

Brunnberg (U.S. Patent No. 6,880,555)

Claims 1, 14 to 16, 18 to 20, 32 to 35, and 73 to 83 were rejected under 35 U.S.C. §102(e) as being anticipated by Brunnberg (U.S. Patent No. 6,880,555).

Applicants respectfully submit that the inhaler disclosed in Brunnberg is breath actuated, i.e. a blister is pierced in response to a user inhaling through a mouthpiece, rather than in response to operation of an actuator. In view of the present Office Action, Applicants believe that the Examiner may consider that the components of the device disclosed in Brunnberg, which cause a blister to be pierced in response to the user's inhalation, can together be considered to form an actuator which is operable to sequentially move a blister into alignment with a piercing member and puncture the lid of an aligned blister. However, Applicants respectfully submit that it is clear from the language of claim 1 of the present invention that the actuator of the present invention is NOT operable in response to inhalation by a user because the claim clearly recites that the operations of the actuator are *"such that, when a user inhales through the mouthpiece, an airflow is generated to entrain the dose and carry it via the mouthpiece into the users airway"* thereby making it clear that a user inhales through the

mouthpiece only subsequent to operation of the actuator to align and pierce a blister.
Therefore, operation of the actuator must be achieved by something other than by inhalation.

Therefore, Brunnberg does not show or teach "An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and an actuator pivotally mounted to the housing, said actuator being pivotable to sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister such that, **when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it via the mouthpiece into the user's airway**" as recited in claim 1 of the present invention.

Claim 73 of the present invention recites that the actuator is *"operable, in response to rotation of the cap, to cause the blister piercing member to puncture the lid of an aligned blister"*. However, in Brunnberg, it is inhalation through the mouthpiece which causes the piercing elements to pierce the lid of an aligned blister rather than movement of the protective cover 236. The protective cover 236 fulfills the function of an actuator only to the extent that it comprises a toothed wheel 242 that engages the surface of a blister cartridge and causes it to rotate so as to align a fresh blister with the piercing members formed by elongate body 208 when the protective cover is closed. Although the protective cover 236 has a tongue 238 that engages a holding member 228 when the protective cover 236 is closed, it should be noted that even without the tongue 238, the holding member 228 is prevented from sliding under the bias provided by the pressure spring 226 due to arm 234 that has a ledge that engages with a corresponding ledge on the holding member 228 (see Brunnberg, column 9, lines 7 to 26). The ledge of the arm 234 only moves out of engagement with the ledge of the holding member 228 in response to a pressure difference between the interior and exterior of the inhaler, caused by inhalation. Once disengaged, the holding member 228 is then free to slide forwards under the force of the pressure spring 226 (see Brunnberg, column 9, lines 26 to 39).

Therefore, Brunnberg does not show or teach "An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user, an actuator and, a cap coupled to the actuator, the cap being rotatable to sequentially move each blister into alignment with a blister piercing member, said actuator being **operable, in response to rotation of the cap, to cause the blister piercing member to puncture the lid of an aligned blister** such that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it out of the blister and via the mouthpiece into the user's airway" as recited in claim 73 of the present invention.

In view of the foregoing, withdrawal of the rejection under 35 U.S.C. §102(e), to claims 1, 14 to 16, 18 to 20, 32 to 35, and 73 to 83 is respectfully requested.

Widerstrom (U.S. Patent No. 6,698,425)

Claims 1, 21 to 27, and 71 were rejected under 35 U.S.C. §102(e) as being anticipated by Widerstrom (U.S. Patent No. 6,698,425).

Applicants respectfully direct the Examiner's attention to the current amendment to claim 1. Claim 1 now recites:

An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and an actuator pivotally mounted to the housing, said actuator being pivotable to sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister such that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it via the mouthpiece into the user's airway.

Claim 1 of the present invention requires that the actuator is operable to "*sequentially move each blister into alignment with a blister piercing member*" and "*operable to cause the blister piercing member to puncture the lid of an aligned blister*". Although Widerstrom discloses an actuator (opening means 16), there is no explicit teaching or suggestion that movement of the opening means 16 also sequentially moves each blister into alignment with a blister piercing member. It is noted that

column 6, lines 7 and 8 refers to the roll as being "automatically unwound and advanced through the inhaler" and column 6, lines 30 and 31 refers to advancement that can "easily be achieved by a mechanical ratchet arrangement". However, there is nothing to indicate that this advancement is achieved as a result of operating the opening means 16. Indeed, we consider that reference to the roll as being "automatically unwound" would lead a skilled person away from the invention, as it implies that the roll unwinds without any need for a user to manually operate an actuator for this purpose.

Applicants respectfully submit that the present invention as recited in amended claim 1 is further distinguished from the disclosure in Widerstrom because the opening means 16 are slideably mounted within the device housing rather than pivotally mounted, as required by amended claim 1 of the present invention.

Therefore, Widerstrom does not show or teach "An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and an actuator pivotally mounted to the housing, said actuator being pivotable to **sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister** such that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it via the mouthpiece into the user's airway" as recited in claim 1 of the present invention.

In view of the foregoing, withdrawal of the rejection under 35 U.S.C. §102(e), to claims 1, 21 to 27, and 71 is respectfully requested.

Claim Rejection – 35 U.S.C. § 103

Piper (U.S. Patent No. 5,533,502)

In the Office Action, claims 6 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Piper (U.S. Patent No. 5,533,502).

Claims 6 and 7 indirectly depend from claim 1.

As noted above, Applicants respectfully submit that claim 1, as amended, recites that the actuator is "pivotally mounted to the housing" and also to specify that the actuator is "pivotable" to cause the blister piercing member to puncture the lid of an aligned blister.

Although Piper discloses an actuator (carriage 24), it is only pivotable to enable each blister to be moved into alignment with a blister piercing member and does not pivot in order to pierce an aligned blister. On the contrary, in the device disclosed in Piper, the user must depress the carriage 24 in relation to the cover 12 so that the inlet and outlet conduits puncture the seal of an aligned medicament receptacle, as shown in Figures 3 and 4 and described at column 5, lines 66-67. Notably, compression of the carriage 24 actually ensures rotation of the carriage is prevented because registration keys 46 engage with registration gear 28, as stated at column 6, lines 2 to 5.

Piper does not show or teach "an actuator pivotally mounted to the housing, said actuator being pivotable to sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister" as recited in amended claim 1 of the present invention. Therefore, the inhaler as recited in claim 1 of the present invention is inventive over Piper (U.S. Patent No. 5,533,502).

For the foregoing reasons, Applicants submit that Piper (U.S. Patent No. 5,533,502) does not teach or suggest, or otherwise make obvious, the claimed inhaler recited in claims 6 and 7. Accordingly, the rejection of claims 6 and 7 under 35 USC 103(a) citing Piper (U.S. Patent No. 5,533,502) is respectfully requested to be withdrawn.

Brunnberg (U.S. Patent No. 6,880,555)

In the Office Action, claims 17, 76, 78, 80, 82, and 83 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brunnberg (U.S. Patent No. 6,880,555).

As noted above, Applicants respectfully submit that the inhaler disclosed in Brunnberg is breath actuated, i.e. a blister is pierced in response to a user inhaling through a mouthpiece, rather than in response to operation of an actuator. Applicants respectfully submit that it is clear from the language of claim 1 of the present invention that the actuator of the present invention is NOT operable in response to inhalation by a user because the claim clearly recites that the operations of the actuator are *"such that, when a user inhales through the mouthpiece, an airflow is generated to entrain the dose and carry it via the mouthpiece into the users airway"* thereby making it clear that a user inhales through the mouthpiece only subsequent to operation of the actuator to align and pierce a blister. Therefore, operation of the actuator must be achieved by something other than by inhalation.

Therefore, Brunnberg does not show or teach "An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user and an actuator pivotally mounted to the housing, said actuator being pivotable to sequentially move each blister into alignment with a blister piercing member, said actuator also being pivotable to cause the blister piercing member to puncture the lid of an aligned blister such that, **when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it via the mouthpiece into the user's airway**" as recited in claim 1 of the present invention.

Claim 73 of the present invention recites that the actuator is *"operable, in response to rotation of the cap, to cause the blister piercing member to puncture the lid of an aligned blister"*. However, in Brunnberg, it is inhalation through the mouthpiece which causes the piercing elements to pierce the lid of an aligned blister rather than movement of the protective cover 236. The protective cover 236 fulfills the function of an actuator only to the extent that it comprises a toothed wheel 242 that engages the surface of a blister cartridge and causes it to rotate so as to align a fresh

blister with the piercing members formed by elongate body 208 when the protective cover is closed. Although the protective cover 236 has a tongue 238 that engages a holding member 228 when the protective cover 236 is closed, it should be noted that even without the tongue 238, the holding member 228 is prevented from sliding under the bias provided by the pressure spring 226 due to arm 234 that has a ledge that engages with a corresponding ledge on the holding member 228 (see Brunnberg, column 9, lines 7 to 26). The ledge of the arm 234 only moves out of engagement with the ledge of the holding member 228 in response to a pressure difference between the interior and exterior of the inhaler, caused by inhalation. Once disengaged, the holding member 228 is then free to slide forwards under the force of the pressure spring 226 (see Brunnberg, column 9, lines 26 to 39).

Therefore, Brunnberg does not show or teach “An inhaler comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, a mouthpiece through which a dose of medicament is inhaled by a user, an actuator and, a cap coupled to the actuator, the cap being rotatable to sequentially move each blister into alignment with a blister piercing member, said actuator being **operable, in response to rotation of the cap, to cause the blister piercing member to puncture the lid of an aligned blister** such that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it out of the blister and via the mouthpiece into the user’s airway” as recited in claim 73 of the present invention.

For the foregoing reasons, Applicants submit that Brunnberg (U.S. Patent No. 6,880,555) does not teach or suggest, or otherwise make obvious, the claimed inhaler recited in claims 17, 76, 78, 80, 82, and 83. Accordingly, the rejection of claims 17, 76, 78, 80, 82, and 83 under 35 USC 103(a) citing Brunnberg (U.S. Patent No. 6,880,555) is respectfully requested to be withdrawn.

New Claim 84

New claim 84 recites: “An inhaler according to claim 1, wherein the housing is

configured to receive a coiled strip of blisters and the actuator is pivotable so as to cause the coiled strip of blisters to unwind so as to sequentially move each blister into alignment with said blister piercing member.”

New claim 84 directly depends from independent claim 1. In view of the reasons discussed above with respect to claim 1 and the prior art cited in the present office action, Applicants respectfully submit that none of the prior art references cited in the present Office Action teach or suggest the inhaler as recited in new claim 84 of the present invention.


Specifically with respect to the Piper reference cited in the present Office Action, new claim 84 recites that the housing is configured "to receive a coiled strip of blisters" and that the actuator is pivotable "so as to cause the coiled strip of blisters to unwind so as to sequentially move each blister into alignment with said blister piercing member". Applicant respectfully submit that the Piper reference as recited in the present Office Action makes no reference to the inhalation device as being suitable for, or configured, so as to house a coiled strip of blisters which are unwound by the actuator. On the contrary, the blisters are formed on a circular disc rather than in strip form. The disc-type device of Piper is therefore inherently very different to the coiled strip-type device of the present invention.

Conclusion

An early and favorable action on the merits is earnestly requested.

Respectfully submitted,

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